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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,168	12/02/2003	Charlotte Moira Norfor Allerton	PC25420A	6748

28523 7590 05/31/2006

PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER

GRAZIER, NYEEMAH

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/727,168

Applicant(s)

ALLERTON ET AL.

Examiner

Nyeemah Grazier

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**  
**WITHDRAWAL OF FINALITY OF LAST OFFICE ACTION**

**I. ACTION SUMMARY**

The Notice of Appeal filed on March 15, 2006 has been acknowledge and fully considered.

**II. RESPONSE TO THE NOTICE OF APPEAL**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the *finality of that action is withdrawn*.

**III. RESPONSE TO AMENDMENTS**

***A. Election: Response to Restriction/Election (Remarks November 3, 2005)***

Applicant's request regarding rejoinder of method claims has been considered. As stated in the Action mailed on July 1, 2005, the method claims will be rejoined upon allowance of the compound claims. Applicant's election of Group I in the reply filed on November 3, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***B. 35 USC §102 Rejection***

Applicant's arguments, see Remarks, filed November 3, 2005 with respect to 102(b) rejection have been fully considered and are persuasive because the claims have been sufficiently

amended to overcome the rejection. The 102(b) rejections of claims 1-8 and 15 have been obviated.

***C. 35 U.S.C. 112, 2<sup>nd</sup> Rejection***

Applicant's arguments, see Remarks, filed November 3, 2005, with respect to claim 1 Rejection have been fully considered and are persuasive because the claim has been amended. Thus, the 112, 2nd rejection of claim 1 have been obviated.

***D. 35 U.S.C. 103(a) Rejection***

Applicant's arguments, see Remarks, filed November 3, 2005, with respect to 1-8 and 15 has been considered and are not persuasive because the amended claims are obvious over Fisher et al. US 5,077,290. The rejection of claims 1-8 and 15 is maintained. (See Rejection below).

***E. Objections to the Specification and Claims***

Applicant's arguments, see Remarks, filed November 3, 2005, with respect to objections has been considered and are persuasive because applicants have amended the abstract and amended the claims. However, in light of the new rejections and the maintained rejections of record the dependent claims are objected to as depending on a rejected based claim.

**IV. REJECTION**

***35 USC § 103 Rejection***

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1626

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

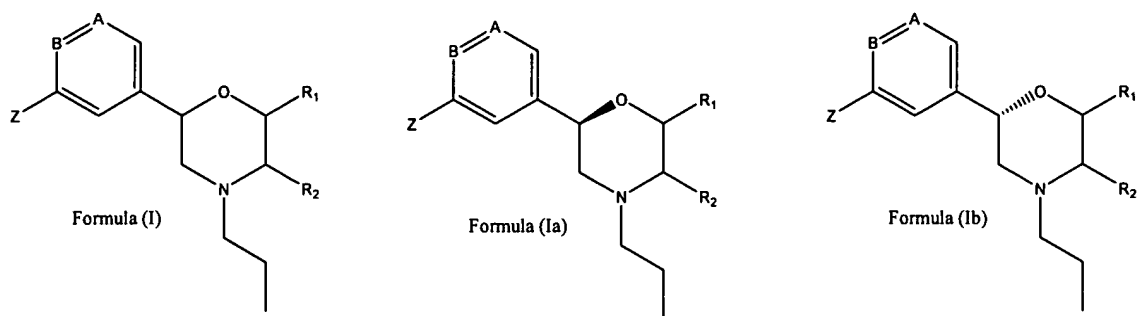
Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. § 103(a). See Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

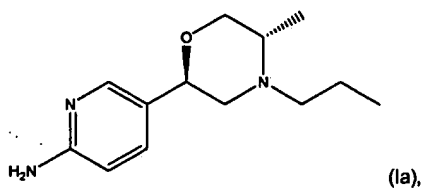
Claims 1-8 and 15-17 are rejected under 35 U.S.C. § 103(a) as being obvious over FISHER, et al. US Patent 5,077,290. The instant invention of claims 1-8, 15 and 16 is rendered obvious where A is nitrogen, B is CY and Y is NH<sub>2</sub> and Z is hydrogen. Claim 16 is also rendered obvious because it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *See, In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *See also, In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity. Finally, Claim 17 is rendered obvious where A is CX and X is NH<sub>2</sub> and Z is hydrogen.

The instant inventions in Claims 1-8 and 15-17 recite the products of formulae (I), (Ia) and (Ib) which have utility as an agonists selective for dopamine D<sub>3</sub> receptors over D<sub>2</sub> receptors useful in the treatment of sexual dysfunction of male and females.

Claims 1-8, 15 and 17 are drawn to the following formulae:

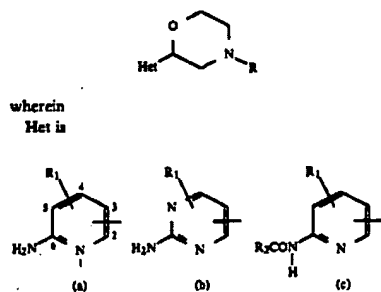


Claim 16 is drawn to the following formula:



**Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Fisher, et al. teaches compounds and the isomeric forms of the formula (I) and there uses as growth promotants, broncodilators, antidepressants and antiobesity agents. See Fisher, et al. at



col. 11, ll. 40-42.

**Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the prior art of *Fisher, et al.* and the instantly claimed compounds is that the *Fisher, et al.* invention, is in scope. Both the instant invention and the prior art are drawn to morpholine substituted pyridines. The difference is that the instant invention is a genus of the prior art.

**Resolving Level of Ordinary Skill in the Pertinent Art**

The pertinent art may be classified as medicinal chemistry and drug discovery. One of ordinary skill in the pertinent art of medicinal chemistry would have the motivation to make and use to instant invention because there is motivation to make in the instant compounds in the abovementioned references which teaches the preferred embodiments of the instant invention. The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**

The prima facie case for obviousness is derived from the preferred teaching of the references. The reference teaches preferred compounds and preferred variable substituents. In the “Detailed Description of the Invention” section of the patent application, amino substituted pyridine (formula “a”) is a preferred compound. (See, *Fisher et al.*, col. 2, line 50). Also, N-lower alkyl is a preferred “R” substitution on the morpholine ring. (See, *Fisher et al.* col. 2, line 55). Thus, the teachings of *Fisher, et al.* reference would have motivated one skilled in the art to make and use in the instant compounds and compositions with the expectation that they would both have the same pharmacokinetic effect.

Thus, the instant invention of claims 1-8, 15 and 16 is rendered obvious where A is nitrogen, B is CY and Y is NH<sub>2</sub> and Z is hydrogen. Claim 16 is also rendered obvious because it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *See, In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *See also, In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity. Finally, Claim 17 is rendered obvious where A is CX and X is NH<sub>2</sub> and Z is hydrogen.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph because the disclosure is not enabling for the prodrug of formula (I) or the prodrug of the pharmaceutically acceptable salt of formula (I). Thus, the specification does not enable one skilled in the pertinent art to make or use the invention commensurate with the scope of the subject matter.

The instant claims recite “a prodrug thereof.” However the Specification does not provide a sufficient description of the structure of the types of prodrugs claimed. Thus, there is no support or written description for prodrugs.



**V. OBJECTIONS**

***Dependent Claim Objections***

Dependent Claims 2-8 and 15 are also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

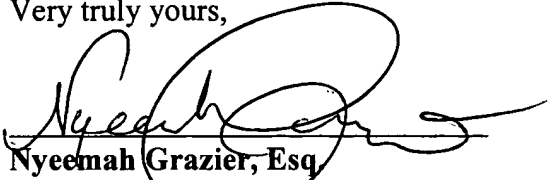
**VI. CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

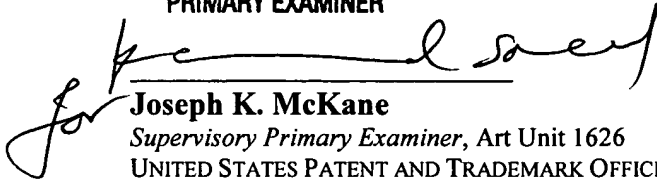
Art Unit: 1626

Very truly yours,



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